New IEEE Standard Enables Data Collection for Medical Applications.

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ABSTRACT

The IEEE has gone to ballot on a "Standard for Medical Device Communications", IEEE P1073. The lower layer, hardware portions of the standard are expected to be approved by the IEEE Standards Board at their December 11-13, 1994 meeting. Other portions of the standard are in the initial stages of the IEEE ballot process. The intent of the standard is to allow hospitals and other users to interface medical electronic devices to host computer systems in a standard, interchangeable manner. The standard is optimized for acute care environments such as ICU's, operating rooms, and emergency rooms. [1]

IEEE General Committee and Subcommittee work has been on-going since 1984. Significant amounts of work have been done to discover and meet the needs of the patient care setting. Surveys performed in 1989 identified the following four key user requirements for medical device communications:
1) Frequent reconfiguration of the network.
2) Allow "plug and play" operation by users.
3) Associate devices with a specific bed and patient.
4) Support a wide range of hospital computer system topologies.
Additionally, the most critical difference in the acute care setting is patient safety, which has an overall effect on the standard. The standard that went to ballot meets these requirements.

The standard is based on existing ISO standards. P1073 is compliant with the OSI seven layer model. P1073 specifies the entire communication stack, from object-oriented software to hospital unique connectors. The standard will be able to be put forward as a true international standard, much in the way that the IEEE 802.x family of standards (like Ethernet) were presented as draft ISO standards.

The standard will allow for data obtained from patient connected devices to be communicated to host computer systems for multiple purposes. Initial applications will be for data collection, enabling the development of systems for technologies such as computer based patient records. Longer term uses of the standard will include closed loop control of patient connected devices and rapid, robust reported of device status changes. The standard has been written to be accommodate these applications and is

extensible for future applications. Prototype hardware has been demonstrated in conjunction with an anesthesia automatic record keeper at SUNY Stony Brook, at the AAMI show in May, 1994. Additional demonstrations have been performed at LDS Hospital and Hewlett Packard in January, 1994; at CEN TC251, Working Group 5 meeting in Madrid in March, 1994; IVAC and Imed in July, 1994; and the American Society of Anesthesiology in October, 1994.

HISTORY

The work of present AMIA members (R. Gardner, M. Shabot), starting in 1982, helped lead to the formation of an Institute of Electrical And Electronic Engineers (IEEE) standards committee in 1984. This committee was charged with writing the "Standard for Medical Device Communications", IEEE P1073. The work of this committee has been on-going since 1984 and been through several major revisions and iterations. The IEEE P1073 committee has also worked closely with several other standards developers to write a communications standard for the patient care setting. Several committees were consulted for expertise in the hospital environment. The work of the ASTM E-31.11 Technical Subcommittees, chaired by Clement McDonald (past President; AMIA), the HL-7 committees, and the X-12 committees helped to validate the requirement for the standard that the IEEE committee was working to solve. The latest revision of the IEEE standard was started in June, 1993, and was agreed to by the committee in January 1994 at a meeting at LDS Hospital. Portions of this standard have finally gone to ballot, and should be approved in December, 1994.

The P1073 Standard is written specifically for medical device communications. The primary focus is on critical care applications where multiple devices are used in a mix and match fashion. This critical care environment has safety, reliability, and ease of use requirements not met by standard computer hardware. The key user requirements identified by the committee in 1989 are: frequent network

reconfigurability; plug and play operation; the ability to associate a device with a specific bed, and thus a specific patient; accommodation of multiple topologies. These goals are all satisfied in the documents that went to ballot. The ability to meet these goals, interoperability of devices from different vendors, and patient safety are the major contributions of the P1073 standard.

INTENT OF THE STANDARD

A major obstacle to development and use of high level applications in hospitals has been the difficulty in getting patient data into the computer systems. The general lack of data communications available from patient connected devices has made data collection very difficult. Additionally, RS-232 connections are NOT standard, frequently giving different data types, on different pins, and changing from device model to device model. This problem exists even for devices produced by a single vendor. The P1073 standards solve the problem by allowing a local or remote Host Computer to collect data from all compliant devices. The standard also achieves interoperability amongst devices from multiple vendors. The standard is designed for the following example scenarios: (1) Automation of the recording and entry of information from medical instruments; (2) Providing clinical personnel better access to device status changes, such as alarms; (3) Automation of adjustments of device settings derived from computed parameters.[1] Use of complaint devices will enable medical informatics professionals to greatly expand their ability to implement systems level solutions.

APPLICATIONS

Medical applications of this technology will grow rapidly. LDS Hospital used previous prototype hardware to develop their HELP System. The improvements in outcomes based on the proper time to administer antibiotics has been previously documented.[2] SUNY Stony Brook has developed an anesthesia automatic record keeper that has been demonstrated using prototype P1073 hardware. This system is also used as a computer assisted instruction tool. The Mayo Clinic has a system in its coronary care units based on IEEE 1073 as of 1987. Cedar Sinai has a critical care system broadly based on IEEE 1073 concepts. Many applications previously presented at SCAMC and other symposia will now be clinically viable due to solution of the hardware problems.

Cantraine has done work in Belgium on computer controlled injection systems.[3] This work has been on going, yet frustrating, due to constantly changing hardware and software requirements. Each new pump, or new pump vendor requires a rewrite of software code, and possible rework of hardware connections. Cantraine is using computers and computer modeling to select appropriate drugs, evaluate the pharmokinetic, prepare infusion sheets, control of delivery, and synchronization of multiple pumps. This is representative of higher level applications, developed by practitioners, that the IEEE P1073 standard will enable.

Typical user developed applications, as produced today, require significant time, effort, and dollars be expended to get interfaces between the desired medical devices. Retrieval and formatting of this data is not routine. As much as one half of the total system design effort can be expended on the seemingly trivial detail of configuring the communications to run the application. This is compounded greatly by the constantly changing nature of data available from devices. Different firmware revisions of the same device may have greatly different data. The system or application designer has to account for the specific complement of devices, and design for the superset of possibilities. This effort has proven extremely challenging, and has stopped many applications from being developed. The solution of this dilemma will be one of the greatest contributions of the IEEE standard. It will allow creative practitioners to create new methods and applications, without needing to learn how every device communicates. Putting all of this creative energy into medical applications, rather than electronic manipulations will prove of tremendous benefit to the practice of medicine.

CLINICAL DEMONSTRATION

Using RS-232 to 1073 converter "matchboxes" and IBM plug-in Bedside Communication Controller (BCC) cards, hardware demonstrations have been performed during surgery at SUNY Stony Brook in New York. The matchboxes were Octagon Micro PC card cages with an XT computer card and a prototype 1073 card. The matchbox was programmed to accept data from a specific device. At Stony Brook, three matchboxes were used. These were programmed to convert data from three different devices to the IEEE 1073 format. The three devices were a Drager Narkomed 3, a Siemens 404 patient monitor, and an Imed Gemini infusion pump.

The matchboxes were controlled by prototype BCC cards plugged into a 80486 based personal computer. The PC was previously programmed to run an anesthesia automatic record keeper application developed at Stony Brook.

The matchboxes were connected to the RS-232 ports of the three devices and configured for the specific data stream of the device. All devices were polled by the matchbox for data to go into a 1,000 byte data table. This table will be replaced by future IEEE standards, 1073.1.x for a Medical Device Data Language, MDDL. The matchboxes then placed this table into their memory for transmission to the BCC. The BCC polled the matchboxes to receive the data table at 1 Megabit per second. The data was Manchester encoded for increased noise immunity. The cables between the matchboxes and BCC cards were then removed and replaced, as well as switched, to demonstrate plug and play, robust operation. The data was automatically collected whenever the cables were connected, with no further operator action.[4]

The prototype hardware used in this demonstration was approximately 80% compliant to the balloted physical layer standard and 60% compliant to the balloted transport profile, due to changes in the draft standard. Subsequent demonstrations were done on 100% compliant prototypes, after the available hardware caught up with the changes to the draft standard. These hardware demonstrations were shown at the AAMI conference, and the ASA Scientific exhibit.

The matchbox configuration used in these demonstrations is typical of what hospitals would need to use with legacy devices with RS-232 ports. These matchboxes convert the RS-232 to IEEE 1073, but need to be programmed for the specific devices they are connected to. Devices introduced after approval of the standard will likely contain the IEEE 1073 interface internally. Demand for such devices will be determined by hospitals. The manufacturers will only add 1073 when the users demand it. Standard products for both matchboxes and internal device communications controllers (DCC) will be available in early 1995.

HOSPITAL IMPLEMENTATION

The IEEE P1073 standard will alter data capture in critical care settings that implement the standard. Each bedside must have one or more BCC's. The BCC is the local communications controller, polling each device in a deterministic, negotiated manner.

The BCC may be an intelligent device like a personal computer or simply a router to a remote host computer. The DCC's in devices cannot "speak" until they are polled. One of the major functions of the BCC is to get unambiguous association of devices with a specific bedside, and thus patient. The first version of the standard specifies a star topology so each device has its own cable to the BCC. This prevents a single wire failure (carts, people, scalpels can sever wires) from bringing the entire network down. Simple devices can use present microcontrollers to implement a 2400 Baud or 9600 Baud data rate in compliance with the standard. The use of ISO standard upper layers and object-oriented technology presents some extra communications overhead, but will prove well worthwhile at the first system change. More complex devices, or host systems, will use the 1 Megabit per second data rate. This will allow most clinical applications to function over the network. This data rate will support ECG waveforms, but is not intended for radiological use.

Higher level BCC functions can be developed to support many present user requirements. BCC's can be programmed to filter data so that only relevant data is sent on to the host computer. Filtering functions such as signal averaging, change data only, or low frequency data recording will be typical BCC filter applications. Many bedside applications can also be programmed into BCC's. Examples are anesthesia record keepers, computer patient records, or closed loop control systems. The likely initial BCC's will be one of three types: a PC with a BCC card; a patient monitor configured as a BCC; a simple, router BCC highly dependent on the host computer.

DCC's will also exist in several forms. New devices will integrate the DCC function with the device. Some vendors will put the DCC internal, while others will offer an external option similar to some present RS-232 options. These will be offered at all three data rates. Legacy devices will be brought into the network through "matchbox" RS-232 to IEEE 1073 converters. These will be programmed for a specific device and firmware revision, and mechanically connected to the device for their life together. Matchboxes will be re-programmable.

Upon physical connection to the network, an automatic connection sequence occurs between the DCC and BCC where device type and status are determined. The device and host negotiate a polling rate based on the request of the device and the

available bandwidth of the BCC. If agreement is reached, the DCC is logically connected to the network and serviced by the BCC. The minimum polling rate is once per second to allow for robust capture of status changes, such as alarms.

There are several optional features for DCC's, while all features are mandatory for BCC's. This is sensible, since a BCC must accept any DCC, while a DCC doesn't need to support higher level features that are not appropriate for the function of the device. DCC's may issue interrupts to the BCC to request emergency service prior to the next scheduled poll. This feature is mandatory in high speed DCC's and is used in the connection establishment sequence. The interrupt function allows for any status changes to be communicated immediately. DCC's may also accept a time synchronization pulse from the BCC. This is used to align the time of day on different devices to within 1 millisecond.

BCC's and DCC's can both issue and receive indications of an intentional disconnect. This lets the device or BCC override alarms when network disconnection was intended. This was a major desire of practitioners.

The present star topology is extremely fault tolerant. The BCC deterministically knows the physical and logical status of all of its communications ports. The BCC will know if a device is still physically connected, even if the device is off or failed. Robust design of devices will allow DCC's to be "alive" even if their host is dead. This will allow for failure isolation in hospital systems, where DCC's can issue messages about the failure of their host to the rest of the system. This feature can be used to build very robust alarms at the system level, rather than the device level. Alarms can also be more robustly designed to allow for sharing of data between devices, or central analysis. Nuisance alarms can be greatly eliminated by comparing data from multiple devices. Even for simple devices, the BCC can use its polling mechanism to determine device operation. Since any working device that is plugged in must respond, and the BCC knows which ports have devices plugged in, it knows of device failures with no ambiguity.

SUMMARY OF THE STANDARD

The P1073 standards follow the Open System Interconnect (OSI) model for communications. The family of standards specifies all seven layers of the ISO communications stack. The documents that are being balloted are as follows:

IEEE P1073 - Framework and Overview of the Standard for Medical Device Communications;

IEEE P1073.1 - Framework and Overview of the Medical Device Data Language;

IEEE P1073.3.1 - Transport Profile;

IEEE P1073.4.1 - Physical Layer for Cable Connected Devices.

The standards are all written as applications or variants of existing ISO Standards, tailored to the bedside environment. It has always been the intention of the committee to use ISO Standards in the sub layers to enable P1073 to be adopted as an ISO Standard for international use. The standard specifies EIA485 transceivers and a defined subset of HDLC with additional capabilities for medical applications for the lower layers. The standard is compatible with IEEE 802.2 to allow alternate transport layers to be useable. The upper layers define a Medical Device Data Language (MDDL), the use of ASN.1, and Basic Encoding Rules (BER). The MDDL is based on object-oriented methodology and defines base classes that are used in other MDDL subsets. These subsets build on each other by means of object-oriented inheritance. MDDL also defines terminology based on SNOMED and the Universal Medical Device Nomenclature System (UMDNS). [5]

The balloted standard specifies a star topology, though others are possible and planned for. The future topologies anticipated are data bus, fiber, and wireless. Use of the ISO model allows for software written for one topology to be useable on the next.

The standard allows highly reliable, deterministic, automatic communications with devices though a Device Communications Controller (DCC). The DCC is internal to a device, or attached to legacy devices. These DCC's are slaves to a Bedside Communication Controller (BCC) which is the hub of the star. The star is connected using six wire, hospital unique cables and connectors. Devices may be plugged into any port of a BCC and communications will commence.

The standard offers two data rates, on the same wires. This accommodates simple devices with very low cost 2400 Baud data, and higher performance devices and systems with 1 Megabit. The standard also has several special function wires that allow devices to be time synchronized or to interrupt the polling routines with high priority messages. Finally, there are two wires that provide 12VDC power

sufficient to power the DCC. [6]

CONCLUSION

The IEEE 1073 Standard for Medical Device Communications will begin to be available in early 1995. Standard, off the shelf, hardware will be available to device manufacturers and hospitals alike. The demonstrations performed to date show that the goals of the standard can be met. Plug and play operation of devices from multiple vendors will be achievable. Devices are able to be associated with a specific bedside. The network can be rapidly and frequently reconfigured. The hardware available in 1995 will allow practitioners, manufacturers, and system integrators to concentrate on true value added functions for hospital operations. The effort now being expended by nurses and doctors to write down data can be channeled into patient care. The effort being expended by information systems professionals on device interface can be expended on connecting hospital systems to get greater efficiencies in inventory management, billing, outcomes research, pharmacy operation, and litigation defense. The steps taken in 1994 and 1995 will be small ones, but they will lead to an explosion in hospital data usage in the second half of the decade.

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